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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,281	09/09/2004	Sanford Reich	642P003-US	9199
42754 7590 02/23/2007 NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,281

Applicant(s)

REICH ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/26/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 12-21 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on December 8, 2006.

Applicant's election of group I, claims 1-11, in the reply filed on December 8, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 26, 2004 was filed after the mailing date of the Application on June 28, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/500,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are a broader version of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hakim (U.S. Patent No. 3,886,948).

With respect to **claim 1**: Hakim teaches a system for regulating the flow of cerebrospinal fluid (hereafter, "CSF") from the brain of an individual comprising an implantable controller 60 in the form of a ventricular shunt adapted to be in fluid communication with said cerebrospinal fluid

and having first and second drainage paths 102/104,62, wherein said controller 60 directs the flow of said cerebrospinal fluid into said first or second drainage paths 102/104,62 in response to the inclination of said individual, signaled by contraction of the brain. (Col. 3, lines 57-64, Col. 5, line 67 – Col. 6, line 15)

With respect to **claim 2**: The first drainage path 102/104 is a supine flow path in that it drains in the presence of lower CSF pressure, wherein said controller 60 directs the flow of said fluid into said supine flow path 102/104 when said individual's inclination is supine or substantially supine. (Col. 6, lines 6-15)

With respect to **claim 3**: The second drainage path 62 is an upright flow path, and wherein said controller 60 directs the flow of said fluid into said upright flow path 62 when said individual's inclination is vertical or substantially vertical, as no additional force other than gravity or that provided by the controller valve 69 is necessary for drainage through catheter 62, and slit 108 is not forced open due to excessive pressure from under-drainage. (Col. 3, lines 56-64)

With respect to **claim 4**: The system taught by Hakim further comprises an inclination sensor 24 for sensing the inclination of said individual, and wherein said controller is responsive to said inclination sensor 24. (Col. 3, lines 64-66, Col. 5, lines 19-25, 39-42)

With respect to **claim 5**: The system taught by Hakim further comprises a bi-stable latching valve 69, and wherein said controller 60 directs the flow of said fluid by actuating said latching valve 69 via a hydraulic connection tube 25 to sensor 24 to allow for fluid communication with said first or said second drainage paths 102/104,62. (Col. 3, lines 64-67, Col. 5, lines 35-42)

With respect to **claim 6**: The supine flow path 102/104 comprises a passive low resistance flow path in that it comprises slit 108 which functions as a passive check valve. (Col. 6, lines 6-15)

With respect to **claim 7**: Hakim does not teach a maximum intraventricular pressure of about 15 mm Hg, however since the maximum intraventricular pressure is dictated by the species of patient, which is human in the case of the prior art device of Hakim and the claimed device, the device of Hakim inherently teaches a maximum intraventricular pressure of about 15 mm Hg.

With respect to **claim 8**: The system taught by Hakim further comprises a programmable variable check valve taught by reference to U.S. Patent No. 3,188,142 to Hakim as the upstream end of the check valve pair taught therein (and with respect to valve 69 taught by Hakim in the instant prior art reference) in said second flow path 62, wherein the cracking pressure of said check valve is modified, as is the cracking pressure of valve 69, based on the inclination angle of said individual. (Col. 2, line 67 – Col. 3, line 5, Col. 4, lines 65-67)

With respect to **claim 9**: The cracking pressure is continually modified to maintain a relatively stable intraventricular pressure for a range of inclination angles. (Col. 2, line 67 – Col. 3, line 5)

With respect to **claim 10**: Stable intraventricular pressure is 45 mm H₂O (3.31 mm Hg) as taught by Hakim, which is between 5 and -5 mm Hg. (Col. 2, line 67 – Col. 3, line 2)

With respect to **claim 11**: The controller 60 implanted in said individual further comprises: an inlet connection; an outlet connection spaced from said inlet connection; an inlet cannula 50

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with a distal and proximal end, wherein said distal end of said inlet cannula 50 is located near the ventricle 56 of the brain and said proximal end of said inlet cannula is connected to said inlet connection of said controller 60; and an outlet cannula 62 with a distal and proximal end, wherein the location of said distal end of said outlet cannula is the peritoneal space, and said proximal end of said outlet cannula is connected to said outlet connection of said controller 60.

(Fig. 1, Col. 3, lines 56-64)


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER



Melanie J Hand
Examiner
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